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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 632,149	08 03 2000	R. Andrew Cuthbertson	A-59553-2 DAV/JJD	1941

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03 11 2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/632,149

Applicant(s)

CUTHBERTSON, R. ANDREW

Examiner

Quang Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 13-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 15
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Interview Summary

Application No.

09/632,149

Applicant(s)

CUTHBERTSON, R.
ANDREW

Examiner

Quang Nguyen, Ph.D.

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All participants (applicant, applicant's representative, PTO personnel):

(1) Richard F. Trecartin.

(3) Dave Nguyen.

(2) Anna Gill.

(4) Quang Nguyen.

Date of Interview: 11 February 2002.

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.


Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussions were focused on the amendments to the pending claims so that they would be in conditions for allowance. Mr. Trecartin needs to consult with Applicant for the approval of suggested amendments.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.


DAVE T. NGUYEN
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an
Attachment to a signed Office action

Examiner's signature, if required

DETAILED ACTION

In light of the totality of the prior art at the effective filing date of the present application along with the disclosure of the instant specification, a new ground of rejection is necessitated by new issues that were not previously raised in the previous Office Actions. As a result, the finality of an Office Action mailed on 05/22/01 in Paper No. 7 is withdrawn.

Applicant's first submission after final filed on 05/22/01 has been entered.

Amended and new claims 13-24 are pending in the present application.

In the amended claim 13, the preamble is not consistent with the body of the claim. While the preamble recites a method of alleviating the degeneration of ocular cells, the body of claim 13 and its dependent claims 14-21 recite genetic ocular diseases. For the purpose of a compact prosecution, claims 13-21 are interpreted as a method of alleviating the degeneration of ocular cells in a genetic ocular disease. Similarly, while the preamble of claim 22 recites a method of alleviating the degeneration of ocular cells, the body of claim 22 recites an ocular lysosomal storage disease. For the purpose of a compact prosecution, claim 22 is interpreted as a method of alleviating the degeneration of ocular cells in an ocular lysosomal storage disease.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 13-21, drawn to a method of alleviating the degeneration of ocular cells in a genetic ocular disease, said method comprising directly

contacting an ocular cell *in situ* with an exogenous nucleic acid under conditions permissive for the direct uptake of said exogenous nucleic acid, said exogenous nucleic acid encoding a protein associated with said ocular disease, whereby said exogenous nucleic acid is expressed in said ocular cell, classified in class 514, subclass 44.

- II. Claim 22, drawn to a method of alleviating the degeneration of ocular cells in an ocular disease wherein the disease is lysosomal storage disease utilizing an exogenous nucleic acid encoding a protein associated with said ocular disease, said method, classified in class 514, subclass 44.
- III. Claims 23 and 24, drawn to a method of alleviating an ocular wound or alleviating an ocular wound after surgery utilizing an exogenous nucleic acid encoding a protein useful in alleviating the ocular wound, classified in class 514, subclass 44.

Should Group I be elected, further **group restriction** is required because claim 13 links a plurality of disclosed patentably distinct genetic ocular diseases that lack the unity of invention. The following ocular genetic diseases have no common underlying genetic mutations causing the diseases or symptoms or disease progression courses: (a) autosomal retinitis pigmentosa, (b) autosomal dominant retinitis punctata albescens, (c) butterfly-shaped pigment dystrophy of the fovea, (d) adult vitelliform macular dystrophy, (e) Norrie's disease, (f) blue cone monochromasy, (g) choroideremia, and (h) gyrate atrophy. For examples, autosomal retinitis pigmentosa is caused by many as

50 different mutations in the rhodopsin gene, autosomal dominant retinitis punctata albescens is associated with a mutation in the peripherin/RDS gene, gyrate atrophy is involved with more than 60 different mutations in the mitochondrial enzyme ornithine aminotransferase, and Norrie's disease, blue cone monochromasy and choroideremia are caused by different genetic mutations.

The restriction requirement between linked inventions is subject to the non-allowance of the linking claim 13. The restriction requirement between linked inventions is subject to the non-allowance of the linking claim(s), 13.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132 (CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different

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methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: The methods in groups I-III are distinct and they are not required one for the other. They require different starting materials (e.g., a patient with a genetic ocular disease in Group I, a patient with an ocular lysosomal storage disease in Group II, and a patient with an ocular wound which is not even a disease let alone a genetic disease in Group III, together with different exogenous nucleic acid molecules encoding for proteins associated with or appropriate for the different ocular diseases or ocular wounds) and different desired therapeutic endpoints.

Because these inventions are distinct for the reasons given above and require separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Quang Nguyen, Ph.D.


DAVE T. NGUYEN
PRIMARY EXAMINER